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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522,524, and 556

Animal Drugs, Feeds, and Related Products; Doramectin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of two supplemental new animal drug applications (NADA's) filed by Pfizer, Inc. The supplemental NADA's provide for added use of doramectin in cattle for injectable use for additional persistent efficacy for treatment and control of certain gastrointestinal roundworms and lungworms and for topical use for treatment and control of horn flies.

EFFECTIVE DATE: (*Insert date of publication in the* **Federal Register.)**

FOR FURTHER INFORMATION CONTACT: Estella Z. Jones, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pi., Rockville, MD 20855, 301-827-7575.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017–5755, filed supplemental NADA 141 –061 that provides for subcutaneous and intramuscular use of Dectomax® (doramectin) 1 percent injectable solution in cattle to control infections and to protect from reinfection with *Cooperia oncophora* for 14 days and *Oesophagostomum radiatum* for 28 days after treatment. The new persistent use is in addition to the currently approved use in cattle for treatment and control of various gastrointestinal roundworms, lungworrns, eyeworms, grubs, sucking lice, and mange mites, and to control infections and to protect from reinfection with *Ostertagia ostertagi* for 21 days and C'. *punctata* and *Dictyocaulus viviparus* for 28 days after treatment.

Pfizer, Inc., also filed supplemental NADA 141 –095 that provides for topical use of Dectomax® (doramectin) 0.5 percent pour-on in beef and nonlactating dairy cattle to treat and control horn flies (*Haematobia irritans*) in addition to its use for treatment and control of gastrointestinal roundworms, lungworms, eyeworms, grubs, biting and sucking lice, and mange mites, and to control infections and to protect from reinfection with C. *oncophora* and *Dictyocaulus viviparus* for 21 days, and O. *ostertagi*, C. *punctata*, and O. *radiatum* for 28 days after treatment.

The supplemental NADA's are approved as of October 25, 1998, and the regulations are amended in 21 CFR 522.770(d)(1)(ii) and 524.770(d)(2) to reflect the approvals. The basis of approval is discussed in the freedom of information summaries.

In addition, a tolerance for doramectin and its residues in cattle muscle has not been previously established. Also, the acceptable daily intake (ADI) for doramectin has not been previously codified. At this time, the regulations are amended in 21 CFR 556.225 to provide for a tolerance for doramectin residues in cattle muscle and an ADI.

In accordance with the freedom of information provisions of21 CFR part 20 and 514.11 (e)(2) (ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), these supplemental approvals for food-producing animals qualify for 3 years of marketing exclusivity beginning October 25, 1998, because the supplements contain substantial evidence of the effectiveness of the drug involved, any studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval of the supplemental applications and conducted or sponsored by the applicant. Exclusivity applies only to the added indication for use of doramectin injection to control infections

and to protect cattle from reinfection with C. *oncophora* for 14 days and O. *radiatum* for 28 days after treatment, and for doramectin topical for the treatment and control of horn flies (H. *irritans*).

The agency has determined under 21 CFR 25.33(a)(l) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects

21 *CFR Parts 522 and 524*

Animal drugs.

21 *CFR Part 556*

Animal drugs, Foods.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegate to the Center for Veterinary Medicine, 21 CFR parts 522, 524, and 556 are amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 522.770 is amended by revising paragraph (d)(1)(ii) to read as follows:

§ 522.770 **Doramectin.**

* * * * *

(d) * * *

(1) * * *

(ii) *Indications for use.* For treatment and control of gastrointestinal roundworms, lungworms, eyeworrns, grubs, sucking lice, and mange mites. To control infections and to protect from

reinfection with *Cooperia oncophora* for 14 days, *Ostertagia ostertagi* for **21** days, and C. *punctata*, *Oesophagostomum radiatum*, and *Dictyocaulus viviparus* for 28 days after treatment.

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PART 524-OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for21 CFR part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

4. Section 524.770 is amended by revising paragraph (d)(2) to read as follows:

§ 524.770 Doramectin.

* * * * *

(d) * * *

(2) *Indications for use.* For treatment and control of gastrointestinal roundworms, lungworms, eyeworms, grubs, biting and sucking lice, horn flies, and mange mites, and to control infections and to protect from reinfection with *Cooperia oncophora* and *Dictyocaulus viviparus* for 21 days, and *Ostertagia ostertagia*, *C. punctata*, and *Oesophagostomum radiatum* for 28 days after treatment.

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PART 556-TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

5. The authority citation for21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

6. Section *556.225* is revised to read as follows:

§ 556.225 Doramectin.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of doramectin is 0.75 microgram per kilogram of body weight per day.

(b) Tolerances-(1) *Cattle.* A tolerance of 100 parts per billion is established for parent doramectin (marker residue) in liver (target tissue) and of 30 parts per billion for parent doramectin in muscle.

(2) *Swine*. A tolerance is established for parent doramectin (marker residue) in liver (target tissue) of 160 parts per billion.

Dated: Dec 2 1998

December 2, 1998

Andrew J. Beaulieu

Andrew J. Beaulieu
Acting Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

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